DETAILED ACTION

Claims 1-5 are pending and presented for examination on the merits.

Claim Objections

Claims 2-5 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 2-5 merely state an intended use of the composition of claim 1, but fail to further limit the composition itself.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/719,960. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of 11/719,960 anticipates the instant claims. The '960 application is drawn to a composition comprising a proanthocyanidin. The instant application is drawn to a pine bark extract. A proanthocyanidin is a pine bark extract because it is something which is extracted from pine bark. This is evidenced by the instant specification on, for example, page 9.

Claims 1-5 are also provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-16 of copending Application No. 11/721,710. The claims of the instant application are anticipated by claims 9-16 of the '710 application because the instant claims are drawn to a composition comprising a pine bark extract and '710 is drawn to a composition comprising a proanthocyanidin, wherein the proanthocyanidin is a pine bark extract.

Claims 1-5 are also provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-20 of copending Application No. 10/991,676. The claims of the instant application are anticipated by claims 5-20 the '676 application because the instant claims are drawn to a composition comprising a pine bark extract and claims 5-20 of '676 are drawn to a composition consisting essentially of a pine bark extract, among other ingredients.

Claims 1-5 are also provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending

Application No. 11/910,984. The claims of the instant application are anticipated by claims 5-20 the '676 application because the instant claims are drawn to a composition comprising a pine bark extract and claims 1-4 of '984 are drawn to a method of producing a proanthocyanidin containing product comprising the step of extracting pine bark. Thus, the product instantly claimed would be produced by the method of the '984 application.

It is noted that the co-pending applications do not explicitly teach that the pine bark extracts have the same intended use as instantly, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-5 either recite, or depend upon a claim which recites 'a pine bark extract'. It is deemed that Applicant has not set forth a representative number of examples in order to reasonably verify possession of such a potentially enormous number of extracts which would provide for the result achieved by the claims (improving lipid metabolism).

The MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that the claims are broad generics, with respect to *all* extracts. The possible variations of extracts are limitless. Although Applicant has disclosed that the pine bark may be extracted with a mixture of ethanol and water (see specification page 19) in order to provide an extract with the effect claimed, this disclosure if actually a *very few* number in comparison to the enormous, *potentially millions* of types of extracts which could be obtained from pine bark. The reason for this large amount of permutations is because extraction techniques are often coupled in order to obtain a product; for example

1) a water extraction followed by an alcoholic extraction: the product obtained is an extract.

2) a supercritical extraction (CO_2) followed by an alcoholic and then a non-polar solvent extraction (e.g., chloroform): the product is an extract.

3) a benzene extraction followed by a water extraction and chromatographic separation: the product is an extract.

4) a water/chloroform extraction (e.g., in a seperatory funnel), followed by collection of the water layer, chromatographic separation and crystallization of an isolate: the product is an extract.

5) squeezing the plant to obtain a juice: the product is an extract.

6) dipping the plant in an organic solvent to remove the waxy layer: the product is an extract.

Although Applicants state that there is no particular limitation on the method of extraction from pine bark (see specification page 6), Applicants have not demonstrated that they were in possession of a potentially limitless number of extracts which have the therapeutic effect instantly claimed.

The MPEP states that the purpose of the written description requirement is to ensure that the invention had possession, as of the filing date of the application, of the specific subject matter later claimed by him or her. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention.' Lockwood v. American Airlines, Inc., 107 F. 3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F. 2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, no that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F. 3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398. The specification lacks sufficient variety of species of extracts to reflect this variance in the genus since the specification does not provide sufficient examples of such a genus of extracts.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F. 2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984)

(affirming rejection because the specification does "little more than outline [goals] appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of 'extract' and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the entire scope of the claimed invention and thus, this rejection is proper.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a lipid metabolism improving agent, comprising a water and ethanol pine park extract comprising 30% or 40% oligomeric proanthocyanidins as an active component, does not reasonably provide enablement for a lipid metabolism improving agent, comprising all pine bark extracts as an active component.. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (Wands, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination,

but rather is a conclusion reached by weighing many factual considerations" (Wands, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to a lipid metabolism improving agent, comprising a pine bark extract as an active agent. Thus, the claims taken together with the specification imply that Applicants are claiming a lipid metabolism improving agent comprising any or all extracts from pine bark as an active agent.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

The state of the art is unpredictable with regard to plant extracts. The scope of the required enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every operable species is not required. A single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements. *In re Vickers*, 141 F.2d 522, 526-27, 61 USPQ 122, 127 (CCPA 1944); *In re Cook*, 439 F.2d 730, 734, 169 USPQ 298, 301 (CCPA 1971). However, in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. *In re Fisher*, 427 F.2d 833,

839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993*); In re Vaeck*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work (see MPEP § 2164.04)

It is well known in the art that polarity of solvents plays a key role in determining the final product obtained by an extraction. However, because many phytochemicals remain undiscovered, the skilled artisan has to make his best educated guess as to what types of phytochemicals will be successfully extracted with a solvent of a particular polarity. Often times, unless the constituents in a particular plant extract have been well evaluated and documented in the literature, the skilled artisan must adhere to trial and error protocols in order to quantitatively determine phytochemical constituents present in samples obtained from respective extraction procedures. These procedures are common when, for example, a plant or part thereof has been documented in the literature as possessing some medicinal quality. The skilled artisan will attempt numerous extraction protocols in attempt to isolate the particular ingredient which has this medicinal quality. Typically, beginning with the first crude extraction, it is a guess as to weather or not the extract will possess certain phytochemical constituents. It is noted that the Instant specification does not disclose what the active ingredient of the extract is; on the contrary, the specification only teaches certain extracts which provide for the effective ingredient.

Each successive extraction of plant matter yields different products due to the

exclusion of ingredients based on the polarity of the solvents solvating constituents with similar polarities. Subsequently, the properties of each respective product are unpredictable and would need to be evaluated for chemical constituents.

Unpredictability with regard to plant extracts due to their highly complex nature has been well documented in the art. Revilla et al. for example (1998) showed that the ***slightest variations in polarity of solvent and reaction time*** upon grape extraction provided respective products with unique characteristic properties (See Tables 1, 2, 4, 5, 6 and 7). In turn, each product would possess varying pharmacological properties based upon their respective methods of extraction. Further contributing to the unpredictability of plant extracts, it has been determined that in some cases, the active agent is not a single ingredient, but a combination of ingredients working synergistically to provide a therapeutic effect:

> "The blood red sap from the bark of several species of Croton (Euphorbiaceae) are used in traditional medicine in S. Amnerica to treat wounds and a series of diseases including cancer. More than 90% dry weight of the sap consists of mixtures of proanthocyanidins ranging from monomers to heptamers and even to polymers of twenty units. We have established the chemical structures of these oligomers and the monomeric units are either catechin or gallocatechin…In addition, we isolated some novel diterpenoids and a series of simple phenols as minor constituents. As a result of biological tests we have concluded that here is no single ingredient for wound healing but that the whole sap contributes to the healing process" (Phillipson, J. 1999).

Since the art of medicinal plant extracts remains largely unsolved, means for using plant extracts for therapeutic effect is highly unpredictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided an example wherein a water and ethanol extract of pine bark is made which contains 30% oligomeric proanthocyanidins and inhibits lipid absorption (see page 19), a pine bark extract which promotes cholesterol excretion ability containing 40% OPCs (see page 21), a pine bark extract comprising 30% OPCs which reduces body fat (see page 23), and a pine bark extract containing 40% OPCs which inhibits accumulation of fat (see page 24). However, the specification does not provide a means for evaluating a representative number of all pine bark extracts for lipid metabolism improving ability.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by Revilla and Philipson and the high unpredictability and the lack of guidance provided in the specification with regard to all pine bark extracts and their activity as lipid metabolism improving agents, one of ordinary skill in the art would be burdened with undue experimentation to determine all of the solvents and method steps necessary in order to evaluate all pine bark extracts for lipid metabolism activity.

It is the Examiner's position that one skilled in the art could not practice the invention commensurate in the scope of the claims without undue experimentation. It is also noted, considering the *a priori* unpredictability in the art with regard to the

therapeutic activity of plant extracts, that improvement of lipid metabolism with all pine bark extracts is not enabled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al. US 6,372,266.

Suzuki et al. teach a medicinal composition which comprises a pine bark extract (see e.g. col 4, lines 18-40).

Therefore, the reference is deemed to anticipate the instant claims above.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed (i.e. as a lipid metabolism improving agent , however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art

composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELENIE MCCORMICK whose telephone number is (571)272-8037. The examiner can normally be reached on M-F 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia Leith/
Primary Examiner, Art Unit 1655